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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/733,640      | 12/08/2000  | Anthony J. McHugh    | 10322/8             | 2399             |

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| EXAMINER |
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GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                   |                  |
|--|-----------------------------------|------------------|
| <b>Office Action Summary</b>   | Application No.                   | Applicant(s)     |
|  | 09/733,640                        | MCHUGH ET AL.    |
|  | Examiner<br>Sharmila S. Gollamudi | Art Unit<br>1616 |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  |                                   |                  |
| <b>Period for Reply</b>  |                                   |                  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                                   |                  |
| <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>   |                                   |                  |
| <b>Status</b>  |                                   |                  |
| <p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>28 March 2002</u>.</p> <p>2a)<input checked="" type="checkbox"/> This action is FINAL.                    2b)<input type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>   |                                   |                  |
| <b>Disposition of Claims</b>   |                                   |                  |
| <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1-8, 17-38 and 40-47</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>1-8, 17-38 and 40-47</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>   |                                   |                  |
| <b>Application Papers</b>  |                                   |                  |
| <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.<br/> <small>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</small></p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.<br/> <small>If approved, corrected drawings are required in reply to this Office action.</small></p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>  |                                   |                  |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>   |                                   |                  |
| <p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> <li>1.<input type="checkbox"/> Certified copies of the priority documents have been received.</li> <li>2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</li> <li>3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p> |                                   |                  |
| <b>Attachment(s)</b>   |                                   |                  |
| <p>1)<input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u>.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____</p>  |                                   |                  |

## DETAILED ACTION

Amendment A filed on March 28, 2002 is acknowledged.

The Supplementary IDS filed on March 28, 2002 is acknowledged.

Claims 1-8, 17-38, and 40-47 are included in the prosecution of this application.

Claims 9-16 and 39 are cancelled.

### New Rejections made in Light of Amendments and IDS

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 5-7, 17-18, 21-22, 25, 27-34, 36, 38, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al combined with Domb et al, cited prior art.**

#### ***Response to Arguments***

The applicant states that independent claim 1 has been amended to obviate the prior art. Applicant argues that Tipton et al only disclose the use of one polymer in the composition and that Tipton prefers polymers having a low ability to crystallize.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that claims 1 recites a "crystallizable polymer" and not crystallized polymer, which is an intended use limitation. Further, the claims lack the degree of crystallization of the polymer. As the applicant recognizes, Tipton teaches

instant polymers and a mixture of the polymers on column 5, lines 8-50. Further, Tipton teaches polymers having a low degree of crystallization, which is suggestive of an amorphous polymer, as well as a polymer that is crystallizable to a low degree, meaning they still have the ability to crystallize. Additionally, the instant claims do not require the polymers to be in a crystallized state. In regards to the unexpected results argued, the examiner points out that the applicant states the rate of release is dependent on the relative amount of crystallizable and amorphous polymers, the instant do not state the ratio and do not correspond to the apparent unexpected results in Figure 5. Further, the examiner points out that instant claim 1 is generic in respect to the polymers and the unexpected results observed are due to two different and specific polymer combinations or due to the amorphous and crystalline nature of the polymers. The examiner points out that claim 16 claims polyester as the crystallizable polymer and claim 17 claims polyester as the amorphous polymer and the claims do not distinguish the two polymers since crystallizable implies the ability to crystallize, which as discussed above, Tipton teaches.

Tipton et al disclose biodegradable composition containing a polymer or a mixture of polymers (col. 5, lines 8-25), a biocompatible solvent (NMP), and a bioactive agent (Note ex. 2). The reference discloses the method of making the composition (Note Ex. 1-3) and the method of inserting the composition into an organism (Note Example 7).

Tipton et al does not exemplify specific polymer combinations.

Domb et al teach polymer blends suitable for use as carriers of active agents (Note abstract, Tables, and Examples. Further, the reference teaches polymer blends provide a uniform release of a substance over an extended period of time. Further, Domb teaches the rate of release depends on the blends of different polymer and the ratio of constituent polymers (col. 2, lines 31-55)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Tipton et al and Domb et al since both references teach a polymer composition as a carrier for active agents. One would be motivated to combine the two references since Tipton suggests the blending of polymer and Dom teaches and exemplifies different blends of polymers, their miscibility, and the ration of the individual polymer constituents. Further, motivation, Domb teaches that polymer blends provide a uniform release of the active substance over a period of time.

**Claims 2-4, 8, 10-13, 19-20, 23-24, 26, 37, and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al (5792469) combined with Domb et al, cited prior art, further in view of Brodbeck et al (6130200).**

Tipton et al disclose biodegradable composition containing a polymer or a mixture of polymers (col. 5, lines 8-25), a biocompatible solvent (NMP), and a bioactive agent (Note ex. 2). The reference discloses the method of making the composition (Note Ex. 1-3) and the method of inserting the composition into an organism (Note Example 7).

Tipton et al does not teach a biocompatible component solvent, ethyl benzoate as the biocompatible solvent, or an emulsifier.

Brodbeck et al teach a gel composition containing a biocompatible polymer, ethyl benzoate, a biocompatible solvent, an emulsifier, and bioactive agent. Brodbeck et al teach the use of ethyl/benzyl benzoate and a secondary solvent such as NMP. The reference discloses that NMP takes up substantially more water alone than a combination of ethyl/benzyl benzoate and NMP. The decrease in water intake increases the stability of the active agent. (Note Examples 3-4, col. 14, lines 13-55) Brodbeck et al disclose the use of an emulsifier not only to dilute the viscous gel formed by the solvent and the polymer but the emulsifier does not affect the release properties of the system (col. 19, lines 10-20). Further, the reference teaches a kit for administering the composition and the kit allows the agent to be separate from the solvent until its use (col. 7, lines 23-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tipton et al and Brodbeck et al since both teach biodegradable polymer composition for administering bioactive agents. One would be motivated to do so since Brodbeck et al teaches the advantages of using ethyl or benzyl benzoate, using a two solvent system, and an emulsifier in a system such as Tipton et al.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Tipton et al and Brodbeck et al as set forth above and administer the composition via a kit as suggested by Brodbeck et al. One would be motivated to do this since the composition would be kept "fresh" as suggested by Brodbeck et al until its use.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 28, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG  
  
June 25, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

12/20